510(k) Summary

JUL 2 1 2011

PROTEUS™ PTA Catheter with Embolic Capture Feature

Introduction

This document contains the 510(k) summary for the modified PROTEUS™ PTA Catheter with Embolic Capture Feature. The content of this summary is based on the requirements of 21 CFR Section 807.92(c).

Applicant Name and Address

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Official Contact: Ilya Burovoy
Vice President, Regulatory Affairs and Quality Assurance

Summary Preparation Date: June 16th, 2011

Device Name and Classification:

Trade Name:	PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature
Common Name:	Percutaneous Transluminal Angioplasty Balloon Catheter
Classification Name:	Catheter, Percutaneous
Classification:	Class II, 21 CFR 870.1250
Product Code	DQY/LIT

Predicate Device:

The modified PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature is claimed to be substantially equivalent to the following legally marketed predicate device:

- Angioslide eXtra™ PTA Balloon Catheter with Embolic Capture Feature (K090364)

Device Description:

The PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature is an over the wire co-axial dual lumen catheter with a foldable balloon located near the distal atraumatic soft tip.

The PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature consists of a foldable balloon with radiopaque markers which aid in positioning the balloon in the artery during the

angioplasty procedure, the co-axial shaft comprising the inner shaft and the outer shaft, and the handle comprising the handle enclosure, the cylinder, the T-connector, the inflation port, the pulling rod with the guidewire port, and the pulling rod locks.

Following embolic capture, the user can opt to use the PROTEUS™ Particle Visualization Kit (PVK) to facilitate the visualization of the embolic material captured by the PROTEUS™ PTA Balloon Catheter.

Indications for Use:

The PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature is indicated for peripheral transluminal angioplasty and for capture and containment of embolic material during angioplasty, for the femoral, iliac, ilio-femoral, popliteal, tibial, peroneal, and profunda arteries.

The PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature is not intended for use in the renal, cerebral, coronary or carotid vasculature.

Summary of Technological Characteristics

The PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter is an over the wire co-axial dual lumen catheter with a foldable balloon located near the distal atraumatic soft tip. The catheter is compatible with a 0.035" guidewire.

The balloon technological characteristics of the modified version of PROTEUS™ PTA Balloon Catheter are substantially equivalent to those of the unmodified version of the device. The modification that is the subject of this Special 510(k) is the addition of a Particle Visualization Kit (PVK) accessory that is used outside of the sterile field to allow users to visualize embolic particles captured by the embolic capture feature of the catheter.

The modified PROTEUS™ PTA Balloon Catheter overall length, catheter sheath sizing, balloon diameter, balloon length, balloon nominal pressure, balloon rated burst pressure and end hole diameter are identical to the unmodified version of the device.

The embolic capture technological characteristics of the modified PROTEUS™ PTA Balloon Catheter are identical to those of the unmodified version of the device. In both devices the containment and removal of embolic material is achieved by proximal vessel occlusion, by means of an inflatable balloon, and subsequent aspiration of embolic material.

Summary of Non-Clinical Testing

Verification and validation testing of the PROTEUS™ Particle Visualization Kit included simulated use testing.

Conclusion

The Angioslide PROTEUS™ PTA Balloon Catheter is substantially equivalent with respect to the indications for use, technological characteristics, and performance characteristics to the following legally marketed predicate device:

- eXtra™ PTA Balloon Catheter, Angioslide – K090364

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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JUL 2 1 2011

Re: K111750
Trade/Device Name: PROTEUS PTA Balloon Catheter with Embolic Capture Feature
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, LIT
Dated: June 20, 2011
Received: June 22, 2011

Dear Mr. Anselmo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. However, we remind you that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111750

Device Name: PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature

Indications for Use:

The Angioslide PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature is indicated for peripheral transluminal angioplasty and for capture and containment of embolic material during angioplasty, for the femoral, iliac, ilio-femoral, popliteal, tibial, peroneal, and profunda arteries.

The Angioslide PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature is not intended for use in the renal, cerebral, coronary or carotid vasculature.

Prescription Use ___X____ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111750